Endoscope
with disposabl cartridg for the invagination of ndoscopic tube

Description of invention

The invention pertains to the field of medicine, namely to colonoscopy and enteroscopy, but can also be used for industrial endoscopes.

Is known the device under FGR patent No. 3329176, which includes an endoscopic tube, encased in an eversible elastic thin-walled tube which functions as a transporter-invaginator (hereinafter - invaginator) of the first tube. The invaginator in the device patented in FGR is set in long layers parallel to the transported tube. To the drawbacks of this device pertains the inconsequential unreeling of invaginator's layers which is explained by their "sticking together" due to air pressure and inevitable getting of air into spaces between them. Untimely everting of any layer excludes from participation in intubation process other layers located above the everted one.

Is known also the intestinal endoscope under the USSR author's certificate No. 1522466 with an invaginator set in short layers and placed at the right angle with an endoscopic tube, which is transported by it. This endoscope is set as a basis to the present invention and will be taken as a prototype. Endoscope-prototype comprise: - source of light; - source 5 of excessive pressure; - endoscopic tube 3 with eyepiece 1, control bloc 2 with communication branch, stop 11 for spring 10; - invaginator of endoscopic tube 3 which consists of everted part 4 and uneverted part, encased in part 4, at that, the uneverted part of invaginator tightly adjoins to an endoscopic tube and is placed in short layers perpendicularly to it. From the side of uneverted end 7 the invaginator is supported with spring 10, but the place of transition of uneverted part of the invaginator into everted 4 is limited by tip 6. Besides, the endoscope-prototype has: - external seal 13 of tube 3 on which the end 12 of the everted part 4 of invaginator is fixed with ring 16; - rings 8, 9 on the uneverted end 7 of the invaginator; - air-duct 15 with cock 17 for feeding working pressure into cavity 14 of everted part 4 of the invaginator; anal dilator 19. Apart from light and image transmission elements, biopsy channels, channels for gas or liquid supply, an endoscopic tube 3 of the prototype comprises two pairs of closely wound springs containing traction lines which pairwise connects the distal ring of a mechanism for bending the distal end of a tube and rollers for manual extraction of traction lines located in block 2.

The first drawback of the prototype is unreliable functioning of its invaginator - difficulties in introducing endoscopic tube 3 into seal 13 (see 42-53 lines of a.c. No.1522466). The invaginator is to be everted under tip 6, but during invagination the distal part of tube 3 becomes bared. It can be due both to lack of a gap between tube 3 and uneverted part of the invaginator and to a friable structure of the latter, which under the action of air pressure adheres to tube 3. Tube pleats formed during bending of the distal end also prevent free movement of the invaginator along tube 3. As a result the spring is unable to displace the invaginator to

tip 6. In addition, the invaginator's end 7, connected with two rings, ensures poor pressurization of cavity 14.

The second drawback of known endoscopes is that bending of its distal end is possible only until a definite number of flexures of an endoscopic tube. Its end is bent by rotating of two rollers each connected to its pair of traction lines. Springs, which comprise traction lines, on the distal end continue channels in the wall of cardan-joint rings. Ends of traction lines are soldered to the distal ring of the cardan mechanism for bending the distal end of the tube. Outward extraction of traction lines from the spring decreases gaps between cardan rings and forms a small radius of a flexure. Herewith, the distal cardan ring pulls the opposite traction line in distal direction, thus ensuring an increase of space between rings. Difference of lengths of big and small half-circumferences of the tube's bend is a product of «π» and diameter of an endoscopic tube. Japanese authors point out that when 3-4 loops are formed, the distal end of an endoscope is blocked, but biopsy forceps continue to function. This difference is explained by L. Aler formula

$$\frac{Q_1}{Q_2} = e^{a \cdot f},$$

where: «Q_1» - manual power realizing traction lines extraction; «Q_2» - remaining from «Q_1» power, attached to a distal cardan ring or cutters of biopsy forceps; «e» - basis of natural logarithm; «α» - traction line rotations in radians; «f» - friction index between a traction line and a spring. Under fixed values «Q_1» and «f», value «Q_2» depends on value «α», but for two consecutively connected traction lines of an endoscope the latter is twice as large as for one line of biopsy forceps.

The third drawback of the prototype are problems of its maintenance. For recurrent use an endoscope is washed, disinfected and sterilized. However, there are reported cases of infecting patients with AIDS and other infections after endoscopy. Preparation of the endoscope-prototype for work also includes its assembly. The number of detached parts of this endoscope amounts to 10, but its assembly takes about half an hour. Ergonomics of operating existing endoscopes also impede its mastering. Thus, the left hand holds the control bloc, switches its cocks, rotates handles, which bend and fix the distal end of the tube, but the right hand introduces the tube into the intestine.

It has been practically proved that if an endoscope has more than 3-4 loops, it is impossible to introduce biopsy forceps into it and take bioptate. This is the fourth drawback of the prototype.

The objectives of the invention have been: - increase reliability of invagination of an endoscopic tube; - ensure bending of its distal end in flexuous channels; - make maintenance of an endoscope more convenient; - perform biopsy in flexuous channels. Implementation of these objectives will make colonoscopy available to any physician and make it easier for experienced endoscopists.

These objectives have been achieved by the fact that in the composition of an endoscope, which contains: - source of light; - source of pressure; - biopsy forceps; - an endoscopic tube with the control bloc and communication branch, at that the endoscopic tube contains

internally elements for light and image transmission, a channel gas/liquid, a biopsy channel, two pairs of springs with traction lines, which pairwise connect the mechanism for bending the distal end of the endoscopic tube with manual extractors of traction lines located in the control block, but externally a compressed spring placed on tubes distal end, the invaginator, the tip, a mobile seal, an anal dilator, additionally has been included:

- a new cylindrical invaginator, ensuring invagination of an endoscopic tube;
- a disposable cartridge connecting an invaginator with auxiliary elements;
- an endoscopic tube ensuring fixation of a cartridge;
- a mechanism for introduction of tube, ensuring concurrently with a cartridge insertion of a tube;
- a system of extractors-intractors of traction lines for bending the tube's end;
- a biopsy forceps' introduction and extraction system and traction line intensifier of biopsy forceps;
- a desk and pedal units of a control bloc of an endoscopic tube.

A compact hollow cylinder of the invaginator is formed of crumpled and tightly compressed in longitudinal and transverse directions short layers of different forms of an eversible thin-walled tube placed at different angles with the longitudinal axis of an endoscopic tube. The cylinder has recurrent narrowings of an external and widenings of its internal diameter.

A disposable sterile cartridge for invagination consists of a shell which has a projection at its proximal end, comprising: an invaginator; a compressed spring; its fixator; a spring distancer in which the distal seal of the endoscopic tube is located, which is joined to an uneverted end of the invaginator; a condom of the distal part of the endoscopic tube fastened at the proximal end to a spring stop, but at the distal end - to the tip with elements for hermetic joining to the endoscopic tube, at that on the shell is located a proximal seal of the endoscopic tube with the anal dilator with the channel in its wall, but at the distal end of the shell the everted end of the invaginator is fastened. In addition to elements for air-tight joining to the endoscopic tube the tip may have a protective glass and a channel for glass washing.

A novel endoscopic tube is supplemented with: - internal transverse pleats of its external cover; - two air-ducts, the larger one has a lateral opening into the cavity of the proximal seal of the disposable cartridge for invagination, but the smaller - into the cavity of distal and proximal condoms; - areas for air-tight fixation of condoms' ends; - a proximal condom.

The mechanism for introduction of the endoscopic tube consists of the cylinder with two pistons, which are interconnected with distancers and an elastic tube. The cylinder is joined with the cartridge for invagination of the endoscopic tube. The cavity between pistons and the elastic tube is connected to the source of pressure or atmosphere (vacuum) through the cock. The cavity between the distal piston and the proximal seal of the endoscopic tube is connected to the source of vacuum or atmosphere (pressure) through the cock. The cocks can be placed in the pedals but the spring, which returns pistons to their home position can be located in the cavity between the proximal seal of the endoscopic tube and the distal piston.

The system of extraction-intraction of traction lines ensuring management over the endoscopic tube's distal end, has a hydro-manual drive and creates additional power equal to a few grams at the distal end of traction lines. The system includes sources of pressure and vacuum connected to elastic tubes containing liquid and springs with traction lines. Tubes are fixed to springs with thread, but springs are made with steps. At the distal end springs are connected with traction lines. In the control bloc traction lines are attached to manual extractors-intractors of traction lines connected to elements ensuring synchronous feeding of vacuum into the cavity of a manually extracted traction line and feeding of pressure into the cavity of an introduced traction line. At the distal end of the tube and traction line a cylinder/piston unit can be placed or a segment of sylphone, the distal end of which is connected to a traction line. A manual extractor-intractor of traction line could be made in the manner of a rod, but the sources of pressure and vacuum – of a piston and cylinder, positioned on the rod. An element ensuring synchronous feeding of vacuum into the cavity of an extracted traction line and pressure into the cavity of an introduced traction line could be a gear mated with cogs of two rods. As each of two gears is coupled only with its pair of traction lines, the bending of the tube's end is performed in two stages. The cross-piece with a management lever, whose central part has a movable connection with the body of the desk node of control bloc, but ends are attached to four rods, pistons and cylinders, ensures simultaneous bending of the tube's end in any direction.

A system for intraction and extraction of biopsy forceps includes sources of pressure and vacuum, which are connected through a cock to the cavity of the biopsy channel, the entrance to which is sealed with a seal of biopsy forceps, at the distal end of which there is a piston of the biopsy channel. In addition the biopsy forceps have an intensifier of traction lines and contain a flexible hermetic tube, which is connected to sources of pressure and vacuum, but the distal end of the tube and traction lines finishes with a cylinder and a piston respectively. The unit piston/cylinder is possible to replace with a segment of sylphone, the distal end of which is connected to traction lines.

Cocks, feeding pressure into the invaginator and mechanism of tube's introduction have to be placed in the pedal node of the control bloc of the endoscopic tube, but the others - in the desk node.

The graphic materials illustrate the essence of invention, where on the fig. 1 is represented the endoscope with disposable cartridge for invagination, where: a - handle-shaped control bloc; b - distal part of endoscopic tube with mounted cartridge; c - longitudinal section of cartridge; d, e, f - enlarged fragments of fig.1c. On fig. 2 is shown the system of extraction-intraction of traction lines when the distal end of an endoscopic tube is in direct position, where: a - position of system elements comprised in control bloc; b - enlarged fragment of fig. 2a; c - distal part of tube with "bared" system elements (vertical arrows show the top-bottom of endoscopic tube); d – enlarged fragment of fig. 2c. On fig. 3 is represented the system of extraction-intraction of traction lines when the end of an endoscopic tube is bent downwards, where: a - position of elements contained in control bloc; b - enlarged fragment of fig. 3a; c - distal part of endoscopic tube with "bared" elements (horizontal arrows show the direction of traction lines motion); d, e - enlarged fragments of fig. 3c. On fig. 4 are represented: a - control bloc and design of new endoscope; b - cross-piece with lever, rods, pistons and cylinders; c – construction of a mechanism for introduction of endoscopic tube into cartridge; d - system of intraction and extraction of biopsy forceps; e – extraction and intraction system of biopsy forceps.

Specification of numerical markings of figs. 1-4 given at the end of the description is practically similar to graphic materials of the prototype. A novel endoscope includes endoscopic tube 3 with control bloc 2 and communication branch. Air-duct 15 and cock 17 positioned on control bloc 2 or in pedal, connect source of working pressure with opening 21 into the cavity of seal 13, which communicates with cavity 14 of shell 22. The distal part of shell 22 is commensurable in relation to length and diameter to unеverted part of invaginator 23, but the proximal part – to the compressed spring 10. Everted end 12 of invaginator 23 is connected to shell 22 by ring 16. Invaginator 23 has narrowings and widenings 24, as well as gap 25 with distal condom 26. Ends of distal 26 and proximal 27 condoms and corresponding to them places of tube 3 have areas 28 for interconnection and hermetization. Seal 29 on end 7 of invaginator 23 separates cavity 14 from cavity 25, which communicates with the intestinal cavity. A distancer 30 prevents deformation of seal 29 by spring 10. Ends of compressed spring 10 are based on distancer 30 and stop 11 at the end 28 of condom 26. Stop 11, in its turn, is positioned on the projection 31 of shell 22. The distal end of condom 26 ends with tip 6 with channels 32 for washing of protective glass 33 and blowing-up of intestines, as well as an element for connection to endoscopic tube 3. On the border of narrow and broad parts of shell 22 there is an area of intermediate diameter with indented elastic ring 34 for fixation of compressed spring 10. Channel 35 of anal dilator 19 is used for decompression of intestines during intubation. In the tube 3, besides the enumerated, there are elastic tubes 36, 37 comprising springs 38, 39 and traction lines 40, 41. Tubes 36, 37 are connected to springs 38, 39 with thread 42. Near mechanism 43 for bending the distal end of tube 3, ends of tubes 36, 37 are closed with plugs 44, which also connect springs 38, 39 with traction lines 40, 41. Proximal ends of tubes 36, 37 are connected with sources 45 of excess pressure and vacuum. Proximal ends of traction lines 40, 41 are connected with their manual extractors-intractors 46, but the latter - with element 47 which ensures synchronous feeding of vacuum into the cavity of traction line 40 which is being extracted and of pressure into the cavity of traction line 41 which is being introduced. Endoscopic tube 3 has internal pleats 48 of external cover, air-duct 49 with two openings 50 for vacuum fixation of condoms 26, 27 to tube 3 and also has removable sleeve gasket 51. Control bloc 2 has cock 52 of air-duct 49. Seal 13 is hermetically connected to mechanism 53 for introduction of endoscopic tube 3. Mechanism 53 for introduction of tube 3 is operated by pedal 54 but lever 55 realizes bending of tubes end. Cylinder 56, two pistons 57, distancers 58 and elastic tube 59 limit cavity 60, which is connected with source of pressure by means of cock in pedal 54. Cavity 61 comprises return spring 62 and is connected with vacuum by means of cock in pedal 54. Seal 64 and nut 65 are mounted on biopsy forceps 63, but piston 66 is positioned at their distal end. Seat for seal 64 and nut 65 is located at entry 67 to biopsy channel, which is positioned with cock 68 on control bloc 2. Sylphone 69, which serves as source of pressure and vacuum in pneumatic intensifier of traction line of biopsy forceps, can be combined with a handle of biopsy forceps 63.

Marks made on condom 27 and tube 3 serves for their correct positioning. Then mechanism 53 is mounted on tube 3 and cartridge for invagination is fixed. Pressing of cock 52 will ensure vacuum fixation of condoms 26, 27 to tube 3. After introduction of seal 13 into cylinder 56 endoscope preparation for work is completed.

After the patient has been placed on an endoscopic table a cartridge is oiled and introduced into the rectum and its ampoule is examined as if with a rigid rectoscope. The pressure in cavity 14 is raised by pressing cock 17 thus freeing distancer 30 from coupling with fixator 34 and shell 22. Thereby spring 10 is released and it is possible to proceed with invagination of tube 3. Eversion of invaginator 23 and introduction of tube 3 into the colon occurs under working pressure in cavity 14 at the moments of pressing pedal 54. During endoscopy intestines are to be distended. Gas into intestines is constantly supplied through gas/liquid channel of tube 3 and through channel 32 of tip 6 thus preventing intestinal content of getting under protective glass 33. Gas evacuation from intestines occurs through channel 35 of anal dilator 19.

Bending of mechanism 43 is accomplished by means of excessive pressure and vacuum sources 45, manual extractors-intractors 46 of traction lines 40, 41 and by means of elements 47 which ensure feeding of vacuum in the cavity of tube 36 which comprises extracted traction line 40, and feeding of excessive pressure in the cavity of tube 37 containing introduced traction line 41. Due to vacuum elastic tube 36 and spring 38 are shortened. Considering, that their distal end is connected with traction line 40, this shortening relieves its manual extraction. Due to pressure in tube 37 the latter and spring 39 elongates towards executive mechanism 43 thus relieving manual intraction of traction line 41. Thread 42 twisted on tubes 36, 37, connects them with springs 38, 39. Thus, vacuum and pressure which shorten and elongate tubes 36, 37 and springs 38, 39 ensure application of powers to distal ends of traction lines 40 and 41; manual extraction and intraction of traction lines 40, 41 creates synchronous efforts on their proximal ends. Mechanism 43 of tube 3 is bent downwards by the above-mentioned method. During bending of mechanism 43 upwards all above enumerated elements are moved in opposite directions, but bending of mechanism 43 to the left and to the right is implemented by the second pair of traction lines which work similarly. In intermediate positions mechanism 43 is bent by interchangeable application of both pairs of traction lines. Element 47 made in the shape of a cross-piece with lever 55 ensures simultaneous bending of mechanism 43 in any direction.

As during colonoscopy tube 3 repeats all natural flexures of the colon its extubation must not be accelerated. Anal dilator 19 through which extubation is to be conducted eliminates unpleasant sensations caused by this process.

The most practical important version of the invention is a colonoscope with endoscopic tube 3 without biopsy channel. A disposable cartridge ensures an available to all and atraumatic transportation of tube 3 in the colon, condoms 26, 27 protect the patient from infections seated in endoscopic tube 3, but tube 3 - from getting contagious during endoscopy. Ergonomy of handling such colonoscope also makes it available to any physician: during endoscopy a physician in sedentary position, watches the screen, presses pedal cock 17 with one foot, pedal 54 with another, the right hand controls lever

55, but in case of necessity washes the protective glass 33 by pressing on the cock with the left hand. Such colonoscope is necessary firstly for family doctors, gastroenterologists and surgeons for regular screening of colon cancer. Having selected "suspicious" patients out-patient physicians will direct them to an in-patient clinic for conducting biopsy and other thorough examination.

For biopsy a cartridge with tip 6, without glass 33 is used. Having exhausted the possibility of manual insertion of forceps 63, it is necessary by means of seal 64 and nut 65 to hermetize entry 67 into the biopsy channel and connect it by means of cock 68 to the source of pressure. Further insertion of forceps 63 is performed by their manual intraction and due to pressure of liquid or gas on piston 66, but extraction – by switching cock 68 in the position «vacuum» and manual extraction of forceps 63. Due to location of source 69 of pressure and vacuum of traction line intensifier in the handle of forceps, taking of bioptate is made as previously - approach of rings ensures movement of the traction line inwards, but detachment - extraction of the traction line.

Specifications of graphic materials' marks on fig. 1-4 and on fig. of the prototype:

1 - eyepiece (fig. of the prototype only);
2 - control bloc with communication branch:
3 – endoscopic tube;
4 - everted part of invaginator (fig. of the prototype only);
5 - source of working pressure in cavity 14 (fig. of the prototype only);
6 - tip of endoscopic tube 3;
7 - uneverted end of invaginator 23;
8,9 – rings at the end 7 of invaginator (fig. of the prototype only);
10 - compressed spring;
11 - stop for spring 10;
12 - everted end of invaginator 23;
13 – proximal seal of tube 3;
14 - cavity of everted part 4 of invaginator 23;
15 – air-duct for feeding working pressure into cavity 14;
16 - ring, fixing end 12 of invaginator 23;
17- cock of air-duct 15;
18 - manometer (fig. of the prototype only);
19 - anal dilator;
20 - rectum (fig. of the prototype only);
21 – air-duct 15 opening on tube 3;
22 - shell of cartridge for invagination;
23 - invaginator formed in a compact flexible cylinder;
24 - narrowings and widenings of cylinder of invaginator 23;
25 - gap (cavity) between cylinder of invaginator 23 and condom 26;
26 - distal condom of tube 3;
27 - proximal condom of tube 3;
28 - areas on tube 3 and at the ends of condoms 26, 27 for their hermetic connection;

29 – distal seal between tube 3 and end 7 of invaginator 23;
30 - distancer between spring 10 and invaginator 23 comprising seal 29;
31 - projection on shell 22 for stop 11;
32 - channel in tip 6;
33 - protective glass of tip 6;
34 - elastic ring, fixing spring 10 in compressed state;
35 - channel in anal dilator 19;
36 - lower elastic tube of extractor-intractor of traction lines;
37 - upper elastic tube of extractor-intractor of traction lines;
38 - lower spring of extractor-intractor of traction lines;
39 - upper spring of extractor-intractor of traction lines;
40 – lower traction line of extractor-intractor of traction lines;
41 – upper traction line of extractor-intractor of traction lines;
42 - thread fixing elastic tubes 36, 37 to springs 38, 39;
43 – mechanism for bending of distal end of tube 3;
44 - plug closing tubes 36, 37 and connecting springs 38, 39 with traction lines 40, 41;
45 - sources of pressure and vacuum;
46 - manual extractors-intractors of traction lines 40, 41;
47 – element for extraction-intraction of one or two pairs of traction lines;
48 - pleats of external cover of tube 3;
49 – air-duct into cavity of condoms 26, 27;
50 - distal and proximal openings of air-duct 49 on tube 3;
51 - sleeve gasket;
52 – air-duct 49 cock on control bloc 2;
53 –mechanism for insertion of endoscopic tube 3;
54 – pedal for switching on mechanism 53;
55 - lever of element 47, made in a shape of cross-piece;
56 - cylinder of mechanism 53;
57- pistons of cylinder 56;
58 – distancers between pistons 57;
59 - elastic tube, attached to pistons 57;
60 - hermetic cavity, enclosed by elastic tube 59 and pistons 57;
61 - hermetic cavity, enclosed by seal 13 and distal piston 57;
62 - spring returning pistons 57 to home position;
63 - biopsy forceps;
64 - seal of entry 67 into biopsy channel;
65 - nut, fixing seal 64;
66 - piston of biopsy forceps;
67 - entry into biopsy channel;
68 - cock feeding pressure or vacuum into biopsy channel;
69 - source of pressure and vacuum connected with cavity of biopsy forceps 63.